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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	23

DATE MAILED: 02/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/403,429	Shimizu et al.
Examiner	**Art Unit**
Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jan 15, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

(b) ☐ they raise the issue of new matter. (See NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s):
102 (e) rejection has been withdrawn

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attatched.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: *1-7 and 13-19*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). *21*.

11. ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment A filed 10/20/99, Request to Withdraw Attorney filed 06/28/00, Amendment B filed 09/13/00, Amendment C filed 02/23/00, Request for Extension of Time filed 02/23/00, 04/10/00, and 01/15/02, Request for Continued Examination filed 04/10/01, Declaration 1.132 filed 04/10/01, Preliminary Response filed 04/10/01, Amendment D filed 07/14/01, Supplemental Information Disclosure Statement filed 07/14/01 and 01/15/02, Petition in Accordance with the Requirements of 37 C.F.R. 1.97(d) filed 01/15/02, and Request for Reconsideration filed 01/15/02.

Response to Arguments

1. Applicant's request for reconsideration of the examiner's withdrawal of claims 14-17 as being not drawn to the invention has been constructively elected by original presentation for prosecution on the merits has been considered. The Examiner maintains the original withdrawal, because granules and tablets per se are classified in class 424, subclass 464 and 489 are distinct inventive from the coated granules, which classified in class 424, subclass 490. Attention is drawn to applicant's specification on pages 2-3 presents 19 objects of the invention, clearly excluding a coated granule. Furthermore, dosage forms listed on page 12, lines 9-13 fails to include coated granules. Therefore, it is the position of the examiner that clearly applicant considered the inventive concept of a coated granule to be distinct. Discussion of a coated granule does not begin until applicant presents optional and different features on pages 17, and

22-23. The structure of the tablets and granules are different, and their operation is also distinct. For example, the dosage form originally claimed permits release in the acidic environment in the stomach, whereas the enteric coated granules release in the basic environment of the intestines. Clearly applicants contention that the coated granules represent the same technical relationship with tablets or granules would be in error. For these reasons, claims 14-17 remain withdrawn.

This application contains claims 14-17 drawn to an invention nonelected with traverse in Paper No. 18. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Applicant's arguments filed 01/15/02 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus, claims 1-7, and 13-19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ohno et al. US 5,958,453, in view of Shashoua et al. US 5,795,909.

The Declarations under 37 CFR 1.132 filed 01/15/02 have been considered but fail to overcome the rejection of claims 1-7, and 13-19 because no evidence to establish that the claimed low substituted hydroxypropyl cellulose provide any unexpected results. Applicant claimed a rapidly disintegrable dosage, the cited prior art has rapidly disintegrable dosage. Applicant's attention is drawn to column 6, lines 62-67, wherein Ohno discloses a buccal tablet that is completely dissolved within the ranges of about 6 seconds to 60 seconds. The range is clearly with the applicant's desire range discloses in applicant's specification page 27, lines 1-5,

the tablet dissolved from 5 to 50 seconds. In any event, the term rapidly disintegrable does not envision or limit the scope of the claims to a range of 5-50 seconds. Accordingly, the Declarations do not establish any unexpected results over Ohno's invention.

Applicant argues that there's no teaching or suggestion of non-conjugated lansoprazole in Shashoua. In response to applicant's argument that Shashoua fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-conjugated lansoprazole) is not recited in the generic claims. Applicant claims recite "lansoprazole". Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Shashoua does not teach or suggest any solid preparations of active ingredients having a sugar and low substituted hydroxypropyl cellulose. Contrary to the applicant's argument, Shashoua is relied upon solely for the teaching of active ingredient, e.g., lansoprazole, pioglitazone, candesartan, and manidipine in an oral dosage form selected from capsules, tablets, sachets, and lozenges (column 49, lines 28-44).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600